Section II. Remarks

Claims 1-21 have been cancelled herewith, and claims 22-42 have been added. No new matter within the meaning of 35 U.S.C. § 132 has been added.

A. Support For New Claims

Ample support for the new claims is provided in the original disclosure. Examples of specific support for the new claims are identified in the following list.

Claim 22: Pages 3-4, 6, 10; FIGS. 1-10 and related text; claim 1
Claim 23: FIGS. 1-10 and related text
Claim 24: Pages 4, 7; FIGS. 2-3; claims 3-4
Claim 25: Pages 8-11; FIGS. 1-4, 7; claim 6
Claim 26: Page 7; claims 12-14
Claim 27: Pages 6, 11; claim 7
Claim 28: Page 8; claims 8-9
Claim 29: Page 11; claim 15
Claim 30: Pages 7-9; FIG. 3 and related text; claims 18-19
Claim 31: Pages 3-4, 6, 10; FIGS. 1-10 and related text; claim 1
Claim 32: FIGS. 1-10 and related text
Claim 33: Pages 4, 7; FIGS. 2-3; claims 3-4
Claim 34: Pages 8-11; FIGS. 1-4, 7; claim 6
Claim 35: Page 7; claims 12-14
Claim 36: Pages 6, 11; claim 7
Claim 37: Page 8; claims 8-9
Claim 38: Page 11; claim 15
Claim 39: Pages 7-9; FIG. 3 and related text; claims 18-19
Claim 40: Pages 6, 7, 9, 10,
Claim 41 Pages 2-3, 10
Claim 42: FIGS. 1-10 and related text

B. Claim Rejections Under 35 U.S.C. § 102

In the December 8, 2005 Office Action, claims 1-7, 10-13, 15 and 16 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,255,808 to Tobler, et al. ("Tobler"). Additionally, claims 1-5, 7, 10-14, and 17 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,170,712 to Kasboske ("Kasboske").

Since all of claims 1-21 have been cancelled herewith, the foregoing rejections under 1-7 and 10-17 U.S.C. § 102(b) are moot.

C. Claim Rejections Under 35 U.S.C. § 103

In the December 8, 2005 Office Action, claims 8, 9, and 17 were rejected under 35 U.S.C. § 103(a) as obvious over Kasboske; claims 8, 9, and 17 were rejected under 35 U.S.C. § 103(a) as obvious over Tobler; and claim 21 was rejected under 35 U.S.C. § 103(a) as obvious over either Kasboske or Tobler further in view of U.S. Patent No. 3,537,498 to Amand ("Amand").

Since all of claims 1-21 have been cancelled herewith, the foregoing rejections of claims 8, 9, 17, and 21 under 35 U.S.C. § 102(b) are moot.

D. Patentability of New Claims 22-42 Over Kasboske, Tobler, and Amand

New claims 22-42 include three independent claims, namely, claims 22, 31, and 40. Each of the claims is patentably distinct over the references cited by the Examiner in the December 8, 2005 Office Action, namely, Kasboske, Tobler, and Amand (collectively, "the Cited References").

1. Patentability of Claims 22-39

None of the Cited References discloses a centrifuge tube as required by independent claims 22 and 31, as reproduced below.

> **22. A centrifuge tube having a body with a closed distal end, an open proximal end, and integral hinge elements at opposing sides of the body to facilitate compression flattening of at least a portion of the body, wherein the body has a substantially uniform diameter along the open proximal end.**

> **31. A centrifuge tube having a body with a closed distal end, an open proximal end, and integral hinge elements at opposing sides of the body to facilitate compression flattening of at least a portion of the body, wherein the body has a central axis extending through the closed distal end and the open proximal end, the body has an average cross-sectional area in a direction perpendicular to the central axis, and the open proximal end has a cross-sectional area at least as large as the average cross-sectional area.**

Specifically, claim 22 requires that the body have "a substantially uniform diameter along the open proximal end," and claim 31 requires that the "open cross-sectional end [have] a cross sectional area at least as large as the average cross-sectional area." Both of these features directly relate to the primary function of the centrifuge tube – namely, to serve as a container for collection and separation of samples. As noted at page 1 of the application:

> [C]entrifugation processing produces supernatent and pelleted solids, that are amenable to separation, e.g., by decanting of the supernatent liquid from the solids mass in the lower end of the centrifuge tube.

Centrifuge tubes according to various embodiments of the invention include flexural hinges on opposing sides that permit such tubes to be pressed to a flat conformation at the region of local manual deformation. See Application, page 6. As a result of such construction, a specimen-containing swab may be inserted into the centrifuge tube to a point where the user can grasp opposing side surfaces intermediate the opposing side seams and compress the respective sides to

define a narrowed slot opening through which the swab element can be drawn to exude or squeeze liquid-borne specimen out of the swab element for subsequent concentration and analysis by the centrifugation operation. See Application, page 6.

To provide such functionality, centrifuge tubes according to the invention should be adapted to receive a specimen-containing swab and exude liquid-borne sample out of the same, and further adapted for use in a centrifuge for effective concentration and analysis.

Conventional centrifuge tubes typically have a substantially cylindrical form, with or without a conical or other narrowed tip to aid in precipitate compaction. Additionally, many centrifuge tubes typically have a diameter of about one inch or less to permit their use with widely available centrifuges of conventional size, and to avoid the need for excessive amounts of wash or elution liquid.

The requirement of claim 22 that the body have "a substantially uniform diameter along the open proximal end" permits the open proximal end to be sufficiently large to receive a specimen-containing swab element without requiring an unnecessarily large and unwieldy tube that may not be suitable for convenient for centrifugation.

Similarly, the requirement of claim 31 that "the open cross-sectional end [have] a cross sectional area at least as large as the average cross-sectional area" ensures that the open proximal end is sufficiently large to receive a specimen-containing swab element without requiring an unnecessarily large and unwieldy tube that may not be convenient for centrifugation, while recognizing that the body may have a non-uniform cross-sectional area along its length.

Neither of the foregoing requirements of claims 22 or 31 are disclosed or suggested by the cited references.

Tobler is directed to foldable bottles (of various shapes including rectangular, essentially round, rectangular/oval, and square/round transverse cross-sections) "distinguished by good stability in the full and empty state as [they have] a large standing surface" (Tobler, col. 2, lines 3-6). Each bottle has a sloping "upper top surface" 4, 104, 204, 304 with a reduced diameter "pouring part" 5, 105, 205, 305 arranged therein. **Tobler thus teaches that the base should be *large* so as to provide stability, with a sloping upper surface leading to a narrowed mouth to facilitate pouring of liquid from the bottle.** Such features of bottles according to Tobler are **contrary** to the "substantially uniform diameter along the open proximal end" limitation of claim 22, and to "the open cross-sectional end [having] a cross sectional area at least as large as the average cross-sectional area" limitation of claim 31. Furthermore, Tobler specifically teaches the presence of a "large standing surface," making a bottle according to Tobler ill-suited for use with a centrifuge typically having a small aperture size for receiving a centrifuge tube.

Kasboske is directed to containers for holding and facilitating dispensation of substances. Containers according to Kasboske include an accordion-like fold structure that permits the container to be manually deformed but causes part of the container to reposition in a predetermined manner, so that fluid contents may be dispensed without causing permanent deformation of the container. Upright and vertically oriented containers according to Kasboske include a **reduced diameter neck (18, 246) provided on a sloping top wall (19, 244) of the body (12, 242), and a large bottom wall (17, 96, 122) for supporting the container** in an

upright position on a subjacent support surface. Kasboske further provides a horizontally oriented drum container (Fig. 19) having two closed ends with a capped opening 229 offset from accordion folds along the longitudinal sides of the container 200. Kasboske fails to teach any tube having a closed distal end, an open proximal end, and a body with a substantially uniform diameter along the open proximal end. In the upright and vertically oriented container embodiments disclosed by Kasboske, the reduced diameter neck and sloping top wall of the body are contrary to the "body [having] a substantially uniform diameter along the open proximal end" limitation as required by claim 22, and contrary to the "the open cross-sectional end [having] a cross sectional area at least as large as the average cross-sectional area" limitation of claim 31. Likewise, in the drum embodiment disclosed by Kasboske, the lack of any "open proximal end" is contrary to the requirements of claims 22 and 31. Furthermore, Kasboske specifically teaches the presence of a "large standing surface," making a bottle according to Kasboske ill-suited for use with a centrifuge typically having a small aperture size for receiving a centrifuge tube.

Amand is directed to a generally rectangular plastic bottle for storing and dispensing sterile medical liquids. While the examiner correctly points out that the plastic bottle of Amand includes concave depressions on exterior surfaces facing one another, the examiner omits mention of the fact that such indentions are **thickened** to permit the container to be manually grasped **without changing the internal volume of the bottle**. In other words, Amand *teaches away* from the use of hinge elements along the outside of a centrifuge tube specifically to permit the tube to be pressed to a flat conformation to permit sample to be extracted from a swab element placed into the interior of a bottle. A reinforced region specifically intended to prevent flexure cannot be construed to disclose a hinge element intended to enable flexure.

Dependent claims 23-30 and 32-39 include all of the limitations of the claims on which they depend (i.e., claims 22 and 31, respectively), and thus are patentably distinct over the cited art for at least the reasons discussed hereinabove.

2. Patentability of Claims 40-42

None of the Cited References discloses an analytical method including the steps of claim 40, as reproduced below:

> **40. An analytical method comprising the steps of:**
> **providing a swab article having a swab element adapted to collect a specimen;**
> **providing a centrifuge tube having a closed distal end, an open proximal end, and a body with integral hinge elements at opposing sides thereof to facilitate compression flattening of at least a portion of the body;**
> **contacting a specimen with the swab element;**
> **inserting the swab element through the open proximal end into an interior portion of the centrifuge tube;**
> **compressively flattening at least a portion of the body to contact and compress the swab element to extract at least a portion of the specimen.**

Specifically, none of the Cited References mention the use of any "swab article" or "centrifuge tube," let alone the performance of the specific method steps utilizing these elements that is the subject of claim 40. To the contrary, each of the Cited References is concerned with storing and dispensing liquids – not the critical purpose of facilitating extraction of a sample from a swab element for subsequent analysis.

Dependent claims 41-42, which are patentably distinct over the Cited References for at least the reasons mentioned in connection with claim 40, provide additional steps not taught or suggested by the Cited References.

In view of the foregoing, patentably distinctions of claims 22-42 over the Cited References have been demonstrated, and allowance of these claims is earnestly solicited.

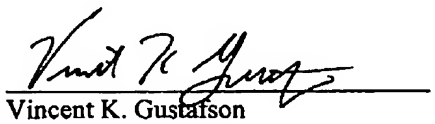
E. (No) Fee Payable for Added Claims

Fees were previously paid for 3 independent claims and 21 total claims (see August 23, 2005 Amendment). By virtue of the current amendment, 3 independent claims and 21 total claims are now pending. If Applicant is mistaken in this regard, however, then any necessary excess claim fee is hereby authorized to be charged to deposit account number 08-3284 of Intellectual Property/Technology Law.

Conclusion

Claims 22-42 as now pending in the application are in form and condition for allowance. Issuance of a Notice of Allowance for the application is therefore requested. If any issues remain outstanding, incident to the formal allowance of the application, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same, in order that this application may be allowed and passed to issue at an early date.

Respectfully submitted,



Vincent K. Gustafson
Reg. No. 46,182
Attorney for Applicant

INTELLECTUAL PROPERTY/ TECHNOLOGY LAW
Phone: (919) 419-9350
Fax: (919) 419-9354
Attorney File No.: 4179-126

Enclosures:

Credit Card Form (form PTO-2038) [1 pg]
Request for Continued Examination (RCE) [1 pg]

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